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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File No. 0-21392

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales (State or other jurisdiction of incorporation or organization)	**Not applicable** (I.R.S. Employer Identification No.)

2 Pembroke House
Upper Pembroke Street 28-32, Dublin 2, Ireland
(Address of principal executive offices)

+353 (0) 1 6699 020
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
American Depositary Shares, each representing one Ordinary Share	The NASDAQ Stock Market LLC
Ordinary Shares, 50 pence par value per share	

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☑ NO ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☑ NO ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☑ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☑
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☑

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2015 was approximately $433.3 million, based upon the closing price on the NASDAQ Capital Market reported for such date.

183,074,916 shares held as American Depository Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 1,936,818 Ordinary Shares, were outstanding as of February 20, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive proxy statement to be filed not later than 120 days after the end of the fiscal year covered by this report.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact contained in this Annual Report on Form 10-K are forward-looking statements, including statements regarding the progress and timing of our clinical programs, regulatory filings and commercialization activities, and the potential clinical benefits, safety and market potential of our product candidates, as well as more general statements regarding our expectations for future financial and operational performance, regulatory environment, and market trends. In some cases, you can identify forward-looking statements by terminology such as "may," "would," "should," "could," "expects," "aims," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue"; the negative of these terms; or other comparable terminology. These statements include but are not limited to statements regarding the commercial success of Vascepa and factors that can affect such success; interpretation of court decisions; expectation on determinations and policy positions of the United States Food and Drug Administration, or FDA; the expected timing of enrollment, interim results and final results of our REDUCE-IT study; the safety and efficacy of our product and product candidates; expectation regarding the potential for Vascepa to be partnered, developed and commercialized outside of the United States; expectation on the scope and strength of our intellectual property protection and the likelihood of securing additional patent protection; estimates of the potential markets for our product candidates; estimates of the capacity of manufacturing and other facilities to support our products; our operating and growth strategies; our industry; our projected cash needs, liquidity and capital resources; and our expected future revenues, operations and expenditures.

Forward-looking statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from those anticipated by such statements. These factors include, among other things, those listed under "Risk Factors" in Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements contained in this Annual Report on Form 10-K are reasonable, we cannot guarantee future results, performance, or achievements. Except as required by law, we are under no duty to update or revise any of such forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Annual Report on Form 10-K.

Unless otherwise indicated, information contained in this Annual Report on Form 10-K concerning our product candidates, the number of patients that may benefit from these product candidates and the potential commercial opportunity for our product candidates, is based on information from independent industry analysts and third-party sources (including industry publications, surveys, and forecasts), our internal research, and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and based on assumptions made by us based on such data and our knowledge of such industry, which we believe to be reasonable. None of the sources cited in this Annual Report on Form 10-K has consented to the inclusion of any data from its reports, nor have we sought their consent. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. While we believe that such information included in this Annual Report on Form 10-K is generally reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" in Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

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Item 1. ***Business***

References in this report to "Amarin," the "Company," "we," "our" and "us" refer to Amarin Corporation plc and its subsidiaries, on a consolidated basis, unless otherwise indicated.

This Annual Report on Form 10-K includes the registered and unregistered trademarks and service marks of other parties.

Amarin Corporation plc is a public limited company incorporated under the laws of England and Wales. Amarin Corporation plc was originally incorporated in England as a private limited company on March 1, 1989 under the Companies Act 1985, and re-registered in England as a public limited company on March 19, 1993. Amarin Corporation plc changed its name from Ethical Holdings plc in 1999.

Our principal offices are located at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. Our registered office is located at One New Change, London EC4M 9AF, England. Our primary office in the United States is located at 1430 Route 206, Bedminster, NJ 07921, USA. Our telephone number at that location is (908) 719-1315.

For purposes of this Annual Report on Form 10-K, our ordinary shares may also be referred to as "common shares" or "common stock."

Overview

We are a biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

Our lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG □500 mg/dL) hypertriglyceridemia. This FDA-approved indication for Vascepa, known as the MARINE indication, is based primarily on the successful results from the MARINE study of Vascepa in this approved patient population. In considering this approval, FDA also reviewed our successful study of Vascepa in patients with high triglyceride levels (TG □200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which condition we refer to as mixed dyslipidemia. This study is known as the ANCHOR study. Safety data from both the MARINE and ANCHOR studies are reflected in FDA-approved labeling for Vascepa. In January 2013, we began selling and marketing Vascepa in the United States based on the FDA-approved MARINE indication. In August 2015, we also began marketing Vascepa in the United States for the treatment of patients studied in the ANCHOR study based on the federal court declaration described below. Vascepa is available in the United States by prescription only.

We sell Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. We market Vascepa in the United States through our sales force of approximately 150 sales professionals, including sales representatives and their managers. In March 2014, we entered into a co-promotion agreement in the United States with Kowa Pharmaceuticals America, Inc. under which approximately 250 Kowa Pharmaceuticals America, Inc. sales representatives began to devote a substantial portion of their time to promoting Vascepa starting in May 2014.

In February 2015, we announced an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, to develop and commercialize Vascepa capsules in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory. We are also assessing other partnership opportunities for licensing Vascepa in other territories outside of the United States.

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Triglycerides are fats in the blood. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that over 70 million adults in the United States have elevated triglyceride levels (TG ≥150 mg/dL), approximately 40 million adults in the United States have high triglyceride levels (TG ≥200 mg/dL), and approximately 4.0 million people in the United States have severely high triglyceride levels (TG ≥500 mg/dL), commonly known as very high triglyceride levels. Many patients with high triglyceride levels also have diabetes and other lipid level abnormalities such as high cholesterol. The patient condition of having more than one lipid level abnormality is referred to as mixed dyslipidemia. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as "good" cholesterol), and elevated levels of LDL-C (often referred to as "bad" cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

We are currently focused on completing the ongoing REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular outcomes study of Vascepa, which we started in December 2011. REDUCE-IT, a multinational, prospective, randomized, double-blind, placebo-controlled study, is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. Based on the results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus four grams per day of Vascepa will be compared to cardiovascular event rates for patients on stable statin therapy plus placebo. The REDUCE-IT study is designed to be completed after reaching 1,612 aggregate cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached in or about 2017 with study results then expected to be available and published in 2018. An interim review of the efficacy and safety results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the independent data monitoring committee (DMC) to occur during 2016 and it is our expectation that the trial will run to completion. The DMC has been more frequently examining interim reviews of the safety data from the study. Following each of these reviews, the DMC has communicated to us that we should continue the study as planned. We remain blinded to all data from the study. Over 99% of the approximately 8,000 patients targeted for enrollment in the REDUCE-IT study have been enrolled and we have pre-notified all clinical sites in the REDUCE-IT study of our intention to cease patient enrollment soon. Since patient enrollment commenced in 2011, approximately 20,000 patient years of study experience have been accumulated in REDUCE-IT.

In the successful Phase 3 MARINE and ANCHOR clinical trials, Vascepa was studied at a daily dose of 2 grams and 4 grams. We sought approval of Vascepa at the more efficacious 4-gram dose for use in each patient population. These trials demonstrated favorable results in their respective patient populations, particularly with the 4-gram dose of Vascepa, in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in Vascepa-treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

In April 2015, we received a Complete Response Letter, or CRL, from the FDA in response to our supplemental new drug application, or sNDA, that sought approval of Vascepa for use in patients with mixed dyslipidemia, based on the successful ANCHOR study. The CRL followed an October 2013 rescission by the FDA of a special protocol assessment, or SPA, agreement and three failed attempts by us to appeal that rescission at FDA. The FDA has acknowledged the success of the ANCHOR study, which met all primary and secondary

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endpoints. However, FDA determined that there were insufficient data to conclude that drug-induced changes in serum triglycerides could be recognized by the FDA as a valid surrogate for reducing cardiovascular risk in the ANCHOR population for the purpose of regulatory approval of a drug targeted at a triglyceride-lowering indication in this population. The FDA has acknowledged that the standard of proof required by the FDA for approval of a new drug indication is higher than that generally used to inform patient treatment guidelines and that used by physicians in clinical practice. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population and the FDA has encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

In May 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia so long as the promotion is truthful and non-misleading. This use reflects recognized medical practice but is not covered by current FDA-approved labeling for the drug and has thus been considered by FDA to be illegal off-label promotion. In August 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit. The court declaration permits us to promote to healthcare professionals the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data. The FDA did not appeal the court's ruling prior to the October 6, 2015 deadline. The underlying litigation has been stayed for settlement discussion and the parties are working toward settlement. In August 2015, we began to promote Vascepa to healthcare professionals as permitted by this court declaration. While we are permitted to more broadly promote Vascepa based on this court declaration, the FDA-approved labeling for Vascepa did not change based on the court declaration, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required.

Commercialization—United States

We commenced the commercial launch of Vascepa in the United States in January 2013. We commenced sales and shipments of Vascepa at that time to our network of U.S.-based wholesalers. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals, including sales representatives and their managers. Commencing in May 2014, in addition to promotion by our sales representatives, approximately 250 Kowa Pharmaceuticals America, Inc. sales representatives began promoting Vascepa. We also employ various marketing personnel to support our commercialization of Vascepa.

Under our co-promotion agreement with Kowa Pharmaceuticals America, Inc., both parties have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the related agreement. The performance requirements include a negotiated minimum number of sales details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, including no less than 250 Kowa Pharmaceuticals America, Inc. sales representatives and the achievement of minimum levels of Vascepa revenue in 2015 and beyond. First position refers to when a sales representative's primary purpose in detailing is related to Vascepa, while second position refers to when a sales representative's primary purpose in detailing is to promote another product, but they also devote time in the same sales call to promote Vascepa. Kowa Pharmaceuticals America, Inc. has also agreed to continue to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margins that increases during the term. The percentage of aggregate Vascepa gross margins earned by Kowa Pharmaceuticals America, Inc. increased from the high single digits in

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2014, to fifteen percent (15%) in 2015, and is scheduled to increase to the low twenty percent levels in 2018, subject to certain adjustments. The term of this co-promotion agreement expires on December 31, 2018, following which Kowa Pharmaceuticals America, Inc. will be entitled to earn tail royalties equal to declining fractions of the co-promotion fee in effect prior to such expiration for periods ranging from one to three years following such expiration.

Based on monthly compilations of data provided by a third party, Symphony Health Solutions, the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2015 was approximately 192,000 compared to 169,000, 148,000, 130,000, and 126,000 in the three months ended September 30, 2015, June 30, 2015, March 31, 2015, and December 31, 2014, respectively. According to data from another third party, IMS Health, the estimated number of normalized total Vascepa prescriptions for the three months ended December 31, 2015 was approximately 203,000 compared to 176,000, 157,000, 137,000, and 131,000 in the three months ended September 30, 2015, June 30, 2015, March 31, 2015, and December 31, 2014, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions shipped to patients, calculated on a normalized basis (i.e., total capsules shipped divided by 120 capsules, or one month's supply). The data reported above is based on information made available to us from third-party resources and may be subject to adjustment and may overstate or understate actual prescriptions. Timing of shipments to wholesalers, as used for revenue recognition purposes, and timing of prescriptions as estimated by these third parties may differ from period to period. Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results are generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. While we expect to be able to grow Vascepa revenues over time, no such guidance should be inferred from the operating metrics described above. We also anticipate that such sales growth may be inconsistent from period to period. We believe that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could changes in prescriber sentiment and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

The commercialization of pharmaceutical products is a complex undertaking, and our ability to effectively and profitably commercialize Vascepa will depend in part on our ability to generate market demand for Vascepa through education, marketing and sales activities, our ability to achieve market acceptance of Vascepa, our ability to generate product revenue and our ability to receive adequate levels of reimbursement from third-party payers. See "*Risk Factors—Risks Related to the Commercialization and Development of Vascepa*."

In August 2015, we and our co-promotion partner began communicating ANCHOR clinical trial data to targeted healthcare professionals. Such qualified communications are being made pursuant to the August 7, 2015 federal district court declaration allowing truthful and non-misleading promotion of the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data.

Commercialization—Outside the United States

In February 2015, we announced an exclusive agreement with Eddingpharm to develop and commercialize Vascepa capsules in what we refer to as the China Territory, consisting of the territories of Mainland China, Hong Kong, Macau and Taiwan, for uses that are currently commercialized and under development by us in the United States based on the MARINE, ANCHOR and ongoing REDUCE-IT clinical trials of Vascepa.

Under the agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the agreement include up-front and milestone payments to us of up to $169.0

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million, including a non-refundable $15.0 million up-front payment received at closing, and development, regulatory and sales-based milestone payments of up to an additional $154.0 million. Eddingpharm will also pay us tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. We will supply finished product to Eddingpharm under negotiated terms.

We continue to assess other partnership opportunities for licensing Vascepa in other territories outside of the United States.

Research and Development

REDUCE-IT is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. REDUCE-IT is a multinational, prospective, randomized, double-blind, placebo-controlled study designed to assess the cumulative effect on the rate of cardiovascular events for patients treated with Vascepa as an add-on to statin therapy compared to the corresponding rate of cardiovascular events for patients treated with placebo on top of statin therapy. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials.

REDUCE-IT is designed to enroll approximately 8,000 patients and enrollment is over 99% complete. We have pre-notified all clinical trial sites in the REDUCE-IT study of our intention to cease further patient enrollment soon. Since patient enrollment commenced in 2011, approximately 20,000 patient years of study experience have been accumulated in REDUCE-IT.

Completion of the REDUCE-IT study is designed to occur after reaching an aggregate number of cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached in or about 2017 with study results then expected to be available in 2018. An interim review of the efficacy and safety results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the independent data monitoring committee, or DMC, to occur during 2016. As is typical, the statistical threshold for defining overwhelming efficacy on the primary endpoint at the interim analysis is considerably higher than the threshold for defining statistical significance at the end of the study and it is our expectation that the trial will run to completion. In addition, we have instructed the DMC to not recommend stopping the study early based only upon achieving statistical significance for the primary endpoint, but to ensure that statistical significance is also achieved for certain subpopulations before recommending that the study be stopped early for overwhelming efficacy. Amarin remains blinded to all data from the study. Unless overwhelming efficacy and safety is declared by the DMC at the interim look or the study is halted due to a patient safety concern, Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study until the study is complete. The DMC has periodically reviewed unblinded safety data since initiation of the REDUCE-IT study in 2011 and, after each such meeting to date, has recommended that the study be continued as planned. The pre-specified interim review at 60% of the target aggregate number of cardiovascular events will involve a look by the DMC in closed session at all efficacy and safety data available from the REDUCE-IT study at that time. Interim looks by independent DMCs are common in large, long-term outcomes studies. By design, it is most common for cardiovascular outcomes studies not to be stopped upon an interim look.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), known as bad cholesterol) are independently in the causal pathway for cardiovascular disease and (iii) clinical data that suggest substantial triglyceride reduction in patients with elevated baseline triglyceride levels correlates with reduced cardiovascular risk. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not to a single mode of action, such as triglyceride lowering, but

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rather to multiple mechanisms working together. Studies in the scientific literature explore potentially beneficial effects of EPA on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

Commercial Supply

Prior to 2015, all of our active pharmaceutical ingredient, or API, that has been utilized in product sold was manufactured by two suppliers: Nisshin Pharma, Inc., or Nisshin, and Chemport, Inc., or Chemport. A significant portion of such API was purchased from Nisshin at a price that is higher than expected future average API costs. During 2015, we began purchasing API from a third supplier, Finorga SAS, or Novasep. The amount of supply we seek to purchase in future periods will depend on the level of growth of Vascepa revenues and minimum purchase commitments with certain suppliers. We continue efforts to expand, diversify and enhance our commercial supply chain.

Financial Position

We believe that our cash and cash equivalents balance of $107.0 million as of December 31, 2015 is sufficient to fund our projected operations for at least the next twelve months. Depending on the level of cash generated from operations, additional capital may be required to sustain operations.

Lipid Disorders and Cardiovascular Disease

Heart attacks, strokes and other cardiovascular events represent the leading cause of death and disability among men and women in western societies. According to the Heart Disease and Stroke Statistics—2016 Update from the American Heart Association, more than 1 out of every 3 adults in the United States (approximately 86 million) currently lives with one or more types of cardiovascular disease; an estimated 965,000 new or recurrent coronary events and 795,000 new or recurrent strokes occur each year; an estimated 31 million adults □20 years of age have high total serum cholesterol levels (□240 mg/dL), and an estimated 74 million adults □20 years of age have borderline high or high low-density lipoprotein (“bad”) cholesterol, or LDL-C, levels (□130 mg/dL).

In addition to cholesterol, lipoproteins such as LDL also carry fats in the form of triglycerides. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream and has been recognized as an independent risk factor for cardiovascular disease. Triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high density lipoprotein cholesterol (HDL-C; often called “good” cholesterol) and elevated levels of LDL-C. The effect of Vascepa on cardiovascular mortality and morbidity in patients with hypertriglyceridemia has not been determined.

Guidelines for the management of very high triglyceride levels (□500 mg/dL) suggest that reducing triglyceride levels is the primary treatment goal in these patients to reduce the risk of acute pancreatitis. Treating LDL-C remains an important secondary goal. Other important parameters to consider in patients with very high triglycerides include levels of apolipoprotein B (apo B), non-HDL-C, very low density lipoprotein cholesterol (VLDL-C), and HDL-C. The effect of Vascepa on the risk for pancreatitis in patients with hypertriglyceridemia has not been determined.

It is estimated that over 40 million adults in the United States have elevated triglyceride levels ≥200 mg/dL and approximately 3 to 4 million people in the United States have very high triglyceride levels (□500 mg/dL). Since 1976, mean triglyceride levels have increased, in concert with the growing epidemic of obesity, insulin resistance, and type 2 diabetes mellitus. In contrast, mean LDL-C levels have decreased.

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Mixed dyslipidemia refers to a condition in which patients have a combination of two or more lipid abnormalities including elevated triglycerides, low HDL-C, and/or elevated LDL-C. Both hypertriglyceridemia and mixed dyslipidemia are components of a range of lipid disorders collectively referred to as dyslipidemia. Dyslipidemia has been linked to atherosclerosis, commonly referred to as hardening of the arteries.

Limitations of Current Therapies

It is estimated that approximately 4% or less of U.S. adults with triglyceride levels □200 mg/dL are currently receiving prescription medication for lowering triglycerides. Many of these patients are taking statin therapy directed primarily at lowering their LDL-C levels.

The leading prescription treatments to lower triglyceride levels are fibrates (fenofibrate and gemfibrozil), statins and generic forms of an omega-3 fatty acid mixture known as Lovaza® in the United States and as Omacor® in Europe. The use of fenofibrates can lead to abnormal liver function tests (an increase in ALT (alanine transaminase) or AST (aspartate transaminase), which are liver enzymes, and are commonly measured clinically as a part of a diagnostic liver function test to determine liver health), especially when used with statins. The use of gemfibrozil can lead to rhabdomyolysis (severe breakdown of muscles), especially when used with a statin. Lovaza is comprised of omega-3 ethyl esters, which the FDA has described as a complex mixture of eicosapentaenoic acid, or EPA, docosahexaenoic acid, or DHA, and other fatty acids. We believe that DHA may increase LDL-C levels and thereby partially offset one of the typically desired benefits of lipid-lowering therapies, which is lowering LDL-C. Also, in 2012, the FDA required an update to Lovaza product labeling to reflect the risk that Lovaza may increase the frequency of a heart rhythm problem known as atrial fibrillation, or heart flutter. Also, in 2015, the FDA updated the Trilipix® (a fenofibrate) product labeling and removed combination use with statin therapy in mixed dyslipidemia patients as an indication due to a failed outcomes trial.

Potential Benefits and Market Opportunity for Vascepa

Vascepa is comprised of not less than 96% pure icosapent ethyl, or ethyl-EPA, and contains no DHA. We believe that the removal of DHA mitigates against the LDL-C raising effect observed in omega-3 compositions that include DHA. Based on the results of the MARINE trial, Vascepa was the first omega-3 based product to demonstrate statistically significant triglyceride reduction without a statistically significant increase in LDL-C in this very high triglyceride population.

We believe that the results of the MARINE trial and Vascepa's EPA only/DHA-free composition suggest that Vascepa has the potential to become a "best-in-class" triglyceride-lowering agent in the United States and the European Union. If the REDUCE-IT cardiovascular outcomes study is successful, Vascepa could be the first omega-3 based therapy approved for lowering high triglycerides in patients with mixed dyslipidemia and for prevention of cardiovascular events as an add-on to statin therapy in this population.

We believe the potential market for Vascepa is large and growing. We estimate that drug treatment for hypercholesterolemia patients exceeds $66 billion per year in the United States, with sales dominated by statin therapies. U.S. sales of fibrates as a class of products were approximately $3.7 billion in 2015 with generic fenofibrate and gemfibrozil leading the class. U.S. gross sales of prescription omega-3 therapies in 2015 were over $1.4 billion with generic Lovaza leading the class.

Clinical Trials

The MARINE Trial (basis for currently FDA-approved label for Vascepa)

The MARINE trial, the largest study ever conducted with the omega-3 fatty acid ethyl EPA in treating patients with very high triglycerides (□500 mg/dL), was a Phase 3, multi-center, placebo-controlled, randomized, double-blind, 12-week study. Patients were randomized into three treatment arms for treatment with Vascepa 4 gram/day, 2 gram/day or placebo. Patient enrollment in this trial began in December 2009, and enrollment and

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randomization was completed in August 2010 at 229 patients. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. The MARINE study primary endpoint was required to meet a stringent level of statistical significance of 1% ($p < 0.01$) in our Special Protocol Assessment, or SPA, agreement with the FDA.

In November 2010, we reported top-line data for the MARINE trial. In the trial, Vascepa met its primary endpoint at doses of 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 33% ($p < 0.0001$) compared to placebo for 4 grams and 20% ($p = 0.0051$) compared to placebo for 2 grams. The median baseline triglyceride levels were 703 mg/dL, 680 mg/dL and 657 mg/dL for the patient groups treated with placebo, 4 grams of Vascepa and 2 grams of Vascepa, respectively.

In a pre-specified secondary analysis in the subgroup of patients with baseline triglyceride > 750 mg/dL, representing 39% of all patients, the effect of Vascepa in reducing triglyceride levels compared to placebo was 45% for 4 grams and 33% for 2 grams, both statistically significant ($p = 0.0001$ for 4 grams and $p= 0.0016$ for 2 grams, respectively). The median baseline triglyceride levels in this subgroup were 1052 mg/dL, 902 mg/dL and 948 mg/dL for placebo, 4-gram and 2-gram groups, respectively. Twenty-five percent of patients in this trial were also on background statin therapy. These patients had greater median reduction in triglyceride levels, which was also statistically significant.

Importantly, the significant reduction in triglycerides was not associated with a statistically significant increase in median LDL-C compared to placebo at either dose (-2.3% for the 4-gram group and +5.2% for the 2-gram group [both p=NS]). In addition, there was a statistically significant decrease in median non-HDL-C (total cholesterol less so-called "good cholesterol") compared to placebo with both of the Vascepa treated groups (-18% for the 4-gram group [$p < 0.001$] and -8% for the 2-gram group [$p < 0.05$]).

The MARINE trial results also included statistically significant reductions compared to placebo in several important lipid and inflammatory biomarkers, including apo B (apolipoprotein B) (8.5%), Lp-PLA2 (lipoprotein-phospholipase A2) (13.6%), VLDL-C (very low-density lipoprotein cholesterol) (28.6%), Total Cholesterol (16.3%), and hsCRP (high-sensitivity C-reactive protein) (36.0%) at the 4-gram dose. For these achieved endpoints, p-values were <0.01 for most and <0.05 for all. Apo B (apolipoprotein B) is believed to be a sensitive biomarker of cardiovascular risk and may be a better predictor of cardiovascular risk than LDL-C. Lp-PLA2 is an enzyme found in blood and atherosclerotic plaque; high levels have been implicated in the development and progression of atherosclerosis. In a post-hoc analysis of MARINE study data, Vascepa 4 g/day and 2 g/day statistically significantly reduced ApoC-III levels by 25.1% ($p < 0.0001$) and 14.3% ($p=0.0154$) versus placebo, respectively. In the MARINE trial, patients treated with 4 grams per day of Vascepa experienced a significant reduction in median placebo-adjusted lipoprotein particle concentrations of total LDL and small LDL. When looking at lipoprotein particle concentrations and sizes as measured with nuclear magnetic resonance spectroscopy, Vascepa 4 grams per day, compared with placebo, significantly reduced median total LDL particle count by 16.3% ($p=0.0006$), which is an important factor in atherogenesis. LDL particle count and apo B are important risk markers for the prediction of cardiovascular events. Small LDL particle count, which is a common risk factor for cardiovascular events in patients with diabetes, was reduced by 25.6% ($p<0.0001$) compared with placebo. Vascepa 2 grams per day, compared with placebo, significantly reduced median small LDL particle count by 12.8% ($p <0.05$) and reduced median total LDL particle count by 1.1% (NS). LDL particle size did not change significantly for the 2 or 4 gram per day doses.

Vascepa was well tolerated in the MARINE trial, with a safety profile comparable to placebo and there were no treatment-related serious adverse events observed. No patient discontinued treatment of Vascepa during this study due to Vascepa-related adverse events. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either Vascepa dose.

Patients enrolled in the MARINE trial were given the option to be treated with Vascepa for a period of up to 40 weeks after their last dose in the double-blind portion of the trial. Once participants completed the randomized, double blind, placebo-controlled 12-week MARINE registration trial, patients in all three

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randomized groups (4 grams, 2 grams and placebo) were offered the opportunity to participate in the open label extension, or OLE, phase. Patients in the OLE phase received 4 grams per day of Vascepa for a period of up to an additional 40 weeks. As is typical of such extension phases, the OLE phase was not a controlled trial, as differentiated from the randomized, double blind, placebo-controlled 12-week MARINE registration trial. In the OLE phase, participants were not randomized at entry, Vascepa administration was open-label (and thus not blinded), and no placebo group was maintained. Also, once patients entered in the OLE phase, investigators were free to add or modify other lipid-altering nutritional, lifestyle and drug treatment regimens. Given the lack of randomization, the open-label design, the addition of various other lipid-altering drugs and changes to doses of existing lipid-altering drugs, as well as the lack of placebo control, neither we nor our independent advisors were able to draw efficacy conclusions from the data. However, we have concluded that the MARINE OLE phase revealed no new safety signals after an additional 40 weeks of exposure to Vascepa, whether used alone or in combination with other lipid-altering regimens.

The ANCHOR Trial (promoted in the United States under court declaration)

The ANCHOR trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study in patients with high triglycerides (□200 and <500 mg/dL) who were also receiving optimized statin therapy. Patients were randomized into three arms for treatment with Vascepa 4 gram/day, 2 gram/day or placebo. Patient enrollment in this trial began in January 2010, and enrollment and randomization was completed in February 2011 at 702 patients. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment.

In April 2011, we reported top-line results from the ANCHOR trial. The ANCHOR trial met its primary endpoint at doses of 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 21.5% ($p<0.0001$ value) for 4 grams and 10.1% ($p=0.0005$) for 2 grams. The median baseline triglyceride levels were 259 mg/dL, 265 mg/dL and 254 mg/dL for the patient groups treated with placebo, 4 grams and 2 grams of Vascepa per day, respectively. The analysis of subgroups by baseline triglyceride tertiles showed that higher baseline triglycerides resulted in greater triglyceride reductions.

One of the trial's secondary endpoints was to demonstrate a lack of elevation in LDL-C, the primary target of cholesterol lowering therapy. The trial's non-inferiority criterion for LDL-C was met at both Vascepa doses. The upper confidence boundaries for both doses were below the pre-specified +6% LDL-C threshold limit. At the 4-gram dose the upper confidence boundary was below zero (-1.7%) and at the 2-gram dose the upper confidence boundary was close to zero (0.5%). For the 4 grams per day group, LDL-C decreased significantly by 6.2% from baseline versus placebo, demonstrating superiority over placebo ($p=0.0067$). For the 2-gram group, LDL-C decreased by 3.6% from baseline versus placebo ($p=0.0867$), which is not a statistically significant decrease.

Other secondary efficacy endpoints included the median placebo-adjusted percent change in non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B), and lipoprotein-associated phospholipase A2 (Lp-PLA2). The 4-gram dose was associated with statistically significant reductions in non-HDL-C (13.6%, $p<0.0001$), apo B (9.3%, $p<0.0001$), Lp-PLA2 (19%, $p<0.0001$) and high-sensitivity C-reactive protein (hsCRP) (22%, $p<0.001$), at week 12 compared to placebo. A recently published analysis showed that the Vascepa 4-gram daily dose in the ANCHOR study also significantly decreased levels of the inflammatory marker oxidized low-density lipoprotein relative to placebo by 13% ($p < 0.0001$). In a separate, post-hoc analysis of study data, Vascepa 4 g/day statistically significantly reduced ApoC-III levels by 25.1% in MARINE ($p < 0.0001$) and by 19.2% in ANCHOR ($p < 0.0001$) versus placebo.

Vascepa was well tolerated in the ANCHOR trial with a safety profile comparable to placebo and there were no treatment-related serious adverse events observed. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either Vascepa dose. The safety results from the ANCHOR trial are included in the current FDA-approved label for Vascepa.

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In April 2015, we received a Complete Response Letter, or CRL, from the FDA in response to our supplemental new drug application, or sNDA, that sought approval of Vascepa for use in patients with mixed dyslipidemia, based on the successful ANCHOR study. The CRL followed an October 2013 rescission by the FDA of a special protocol assessment, or SPA, agreement and three failed attempts by us to appeal that rescission at FDA. The FDA has acknowledged the success of the ANCHOR study, which met all primary and secondary endpoints. However, FDA determined that there were insufficient data to conclude that drug-induced changes in serum triglycerides could be recognized by the FDA as a valid surrogate for reducing cardiovascular risk in the ANCHOR population for the purpose of regulatory approval of a drug targeted at a triglyceride-lowering indication in this population. The FDA has acknowledged that the standard of proof required by the FDA for approval of a new drug indication is higher than that generally used to inform patient treatment guidelines and that used by physicians in clinical practice. The FDA did not determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population and the FDA has encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

In May 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia so long as the promotion is truthful and non-misleading. This use reflects recognized medical practice but is not covered by current FDA-approved labeling for the drug and has thus been considered by FDA to be illegal off-label promotion. In August 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit. The court declaration permits us to promote to healthcare professionals the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data. The FDA did not appeal the court's ruling prior to the October 6, 2015 deadline. The underlying litigation has been stayed for settlement discussion and the parties are working toward settlement. In August 2015, we began to promote Vascepa to healthcare professionals as permitted by this court declaration. While we are permitted to more broadly promote Vascepa based on this court declaration, the FDA-approved labeling for Vascepa did not change based on the court declaration, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required.

Observed Efficacy of Ethyl-EPA

In Japan, ethyl-EPA is marketed under the product name of Epadel by Mochida Pharmaceutical Co. and is indicated for hyperlipidemia and peripheral vascular disease. Clinical data from Japan suggests that Epadel is effective in reducing triglycerides. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study, or JELIS study, which consisted of more than 18,000 patients followed over multiple years, Epadel, when used in conjunction with statins, was shown to reduce cardiovascular events by 19% compared to the use of statins alone. In this study, cardiovascular events decreased by approximately 53% compared to statins alone in the subset of primary prevention patients with triglyceride levels of □150 mg/dL (median of 272 mg/dL at entry) and HDL-C <40 mg/dL. Epadel has been approved and available by prescription in Japan for over a decade. In 2013, the Japan Ministry of Health approved Epadel for over-the-counter sales. JELIS provides supportive but not conclusive data that EPA drug therapy may reduce major coronary events. JELIS results cannot be generalized to populations outside of Japan due to limitations in the study's design. Further study is needed, such as the REDUCE-IT study, to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

Observed Clinical Safety of Vascepa

Prior to commencing the MARINE and ANCHOR trials, we conducted a pre-clinical program for Vascepa, including toxicology and pharmacology studies. In addition, we previously investigated Vascepa in central nervous system disorders in several double-blind, placebo-controlled studies, including Phase 3 trials in

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Huntington's disease. Over 1,000 patients have been dosed with Vascepa in these studies, with over 100 receiving continuous treatment for a year or more. In all studies performed to date, Vascepa has shown a favorable safety and tolerability profile. In both the MARINE and ANCHOR trials, patients dosed with Vascepa demonstrated a safety profile similar to placebo. There were no treatment-related serious adverse events in the MARINE study or in the ANCHOR study. In the MARINE and ANCHOR trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in Vascepa treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo). There was no reported adverse reaction > 3% and greater than placebo.

In addition to the MARINE and ANCHOR trials, we completed a 28-day pharmacokinetic study in healthy volunteers, a 26-week study to evaluate the toxicity of Vascepa in transgenic mice and multiple pharmacokinetic drug-drug interaction studies in healthy subjects in which we evaluated the effect of Vascepa on certain common prescription drugs. All findings from these studies were consistent with our expectations and confirmed the overall safety profile of Vascepa.

The REDUCE-IT Study (currently ongoing cardiovascular outcomes study)

In August 2011, we reached agreement with the FDA on an SPA for the design of the REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular outcomes study. In May 2013, we amended the patient enrollment criteria within the SPA agreement with the FDA. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the REDUCE-IT study adequately addressed the objectives necessary to support a regulatory submission. An SPA is generally binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy of the drug is identified after the testing begins. Moreover, any change to a study protocol can invalidate an SPA.

In September 2011, we engaged a clinical research organization, or CRO, and began initial trial and clinical site preparation for REDUCE-IT. In December 2011, we announced that the first patient was dosed in the study. The study duration is dependent on the rate of clinical events in the study which rate may be affected by the number of patients enrolled in the study, the epidemiology of the patients enrolled in the study, and the length of time that the enrolled patients are followed.

The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population also receiving statin therapy. REDUCE-IT is a multi-center, prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effectiveness of Vascepa, as an add-on to statin therapy, in reducing first major cardiovascular events in an at-risk patient population compared to statin therapy alone. The control arm of the study is comprised of patients on optimized statin therapy plus placebo. The active arm of the study is comprised of patients on optimized statin therapy plus Vascepa. All subjects enrolled in the study will have elevated triglyceride levels and either coronary heart disease or risk factors for coronary heart disease. This study is being conducted internationally.

REDUCE-IT is designed to enroll approximately 8,000 patients and enrollment is over 99% complete. We have pre-notified all clinical trial sites in the REDUCE-IT study of our intention to cease further patient enrollment soon. Since patient enrollment commenced in 2011, approximately 20,000 patient years of study experience have been accumulated in REDUCE-IT. Completion of the REDUCE-IT study is designed to occur after reaching an aggregate number of cardiovascular events. Based on projected event rates, we estimate the onset of the target aggregate number of cardiovascular events to be reached in or about 2017 with study results then expected to be available in 2018. An interim review of the efficacy and safety results of the trial is scheduled to occur upon reaching 60% of the target aggregate number of cardiovascular events. We currently expect this interim review by the independent data monitoring committee, or DMC, to occur during 2016. As is typical, the statistical threshold for defining overwhelming efficacy on the primary endpoint at the interim analysis is considerably higher than the threshold for defining statistical significance at the end of the study and it

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is our expectation that the trial will run to completion. Amarin remains blinded to all data from the study. Unless overwhelming efficacy and safety is declared by the DMC at the interim look or the study is halted due to a patient safety concern, Amarin personnel will remain blinded to the efficacy and safety data from the REDUCE-IT study until the study is complete. The DMC has periodically reviewed unblinded safety data since initiation of the REDUCE-IT study in 2011 and, after each such meeting to date, has recommended that the study be continued as planned. The pre-specified interim review at 60% of the target aggregate number of cardiovascular events will involve a look by the DMC in closed session at all efficacy and safety data available from the REDUCE-IT study at that time. Interim looks by independent DMCs are common in large, long-term outcomes studies. By design, it is most common for cardiovascular outcomes studies not to be stopped upon an interim look.

Our scientific rationale for the REDUCE-IT study is supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), known as bad cholesterol) are independently in the causal pathway for cardiovascular disease and (iii) clinical data that suggest substantial triglyceride reduction in patients with elevated baseline triglyceride levels correlates with reduced cardiovascular risk. Our scientific rationale for the REDUCE-IT study is also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together. Studies in the scientific literature explore potentially beneficial effects of EPA on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture. The REDUCE-IT study is needed to determine the clinical benefit, if any, of EPA therapy in statin-treated patients with elevated triglyceride levels.

We currently expect that final positive results of the REDUCE-IT study will be required for FDA label expansion of Vascepa. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indications studied in the ANCHOR and MARINE trials such as potential indicated uses for prevention of cardiovascular events, although there can be no assurance as to whether the results of the study will support any such indication.

New Lipid Compounds and other Preclinical Programs

We are also considering development of other next generation compounds based on our internal lipid science expertise, including potential combination and derivative therapies.

In August 2013, we completed dosing of AMR102, a fixed dose combination of Vascepa and a leading statin product. The study is a randomized, open-label, single-dose, 4-way cross-over study to continue testing of the relative bioavailability of AMR102 capsules, Vascepa capsules with the selected statin taken concomitantly, Vascepa taken alone and the selected statin taken alone. The results of this study support the feasibility of AMR102. We have suspended additional development of AMR102 pending FDA approval of label expansion of Vascepa, anticipated to occur no sooner than after FDA review of the results from the REDUCE-IT study.

We believe that Vascepa and other lipid-based compositions may have an impact on a number of biological factors in the body such as anti-inflammatory mechanisms, cell membrane composition and plasticity, triglyceride levels and regulation of glucose metabolism. Currently all other development activities are at formulation or pre-clinical stages.

Manufacturing and Supply for Vascepa

We currently use third-party manufacturers and suppliers to manufacture clinical and commercial quantities of ethyl-EPA, which constitutes the only active pharmaceutical ingredient, or API, within Vascepa, to encapsulate, bottle and package Vascepa and to maintain inventory of Vascepa. The FDA approval of Vascepa in

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July 2012 included the approval of one API manufacturer, Nisshin Pharma, Inc., or Nisshin, and one API encapsulator, Patheon, Inc., or Patheon (formerly Banner Pharmacaps Europe BV). Nisshin and Patheon are the API manufacturer and API encapsulator, respectively, with which we have had the longest working relationships. Their facilities were approved by the FDA following successful preapproval inspections and they remain active producers of Vascepa.

We currently rely on Patheon and Capsugel for the encapsulation of Vascepa and we have an encapsulation agreement with one other qualified commercial API encapsulator.

In addition to purchasing API from Nisshin, we have also purchased API from Chemport, Inc., or Chemport. In December 2012, we announced our submissions of two sNDAs to the FDA seeking approval for Chemport and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. In April 2013, the FDA approved our sNDAs covering Chemport and BASF as additional Vascepa API suppliers. On December 30, 2013, we issued a notice of termination of our API agreement to BASF as a result of BASF's non-compliance with the terms of such agreement period and the agreement subsequently terminated in the first quarter of 2014. BASF remains an approved API supplier. In December 2012, we announced an agreement with an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc., or Slanmhor. We submitted a sNDA in August 2013 seeking FDA approval for this supplier to manufacture Vascepa API and in July 2014 the FDA approved our sNDA for Slanmhor as an API supplier. In July 2014, we terminated the supply agreement with Slanmhor and subsequently, in July 2015, entered into a new supply agreement with Finorga SAS (DBA Novasep), a French company. API manufactured by Finorga (Novasep) was previously approved by the FDA in July 2014.

The API material that constitutes ethyl-EPA is a naturally occurring substance which is sourced from qualified producers of fish oil. A limited number of other manufacturers have the ability, scale, know-how and suitable facilities to produce ethyl-EPA to a similar level of purity. Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer's quality control and manufacturing procedures conform to pharmaceutical current Good Manufacturing Practice, or cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities before regulatory approval of a product candidate, such as Vascepa, and on a periodic basis after the initial approval. In complying with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting, and other regulatory requirements.

Some of our agreements with our API suppliers are exclusive and may include minimum purchase commitments. During 2014 and 2015, we fully met the aggregate minimum purchase requirements for metric tons of API contained in our supply agreements. We may purchase more than the minimum requirements. Certain of these agreements contemplate phased capacity expansion aimed at creating sufficient capacity to meet anticipated demand for API material for Vascepa. These contracts contain provisions for making lesser payments to these suppliers in lieu of purchasing the full minimum purchase requirements.

Our Commercialization Plans

In January 2013, we commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication with a direct sales force of approximately 275 sales representatives. In October 2013, we lowered our number of sales representatives to approximately 130, excluding sales management, in the United States to focus on the sales territories that we believe have demonstrated the greatest potential for Vascepa sales growth. We now market Vascepa in the United States through our sales force of approximately 150 sales professionals, including sales representatives and their managers. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa. We currently target clinicians who are top prescribers of lipid regulating therapies. Commencing in May 2014, in addition to promotion by our sales representatives, approximately 250 Kowa Pharmaceuticals America, Inc. sales representatives began promoting Vascepa in the United States. We also employ various marketing personnel to support our commercialization of Vascepa.

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We are also expanding our commercialization activities to markets outside of the United States through partnering arrangements. In February 2015, we entered into a commercialization agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, related to the development and commercialization of Vascepa in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory. Under this agreement, Eddingpharm is solely responsible for development and commercialization activities in the China Territory and associated expenses. Significant commercialization of Vascepa in the China Territory is several years away.

We continue to assess other partnership opportunities for licensing Vascepa in other territories outside of the United States.

Competition

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our products. It is probable that the number of companies seeking to develop products and therapies similar to our products will increase. Many of these and other existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with or superior to ours. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, which might render our technology and products noncompetitive or obsolete.

Our competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc, which currently sells Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia was approved by FDA in 2004 and has been on the market in the United States since 2005. As described below, multiple generic versions of Lovaza are now available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently sells Tricor® and Trilipix® for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan®, which is primarily used to raise HDL-C, but is also used to lower triglycerides. Generic versions of Tricor, Trilipix, and Niaspan are also now available in the United States. In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. Each of these competitors, other than potentially Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

In April 2014, Teva Pharmaceuticals USA Inc., or Teva, launched a generic version of Lovaza after winning its patent litigation against Pronova BioPharma Norge AS, now owned by BASF, which owns such patents rights. In June 2014 and September 2014, Par Pharmaceutical Inc., or Par, and Apotex Inc., or Apotex, received FDA approval of their respective versions of generic Lovaza. In March 2011, Pronova/BASF entered into an agreement with Apotex to settle its patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, we believe Pronova/BASF granted Apotex a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, the details of which are not known to us. In the first quarter of 2015, Prasco Labs announced it also has a generic version of Lovaza. Also in 2015, two additional manufacturers, AvKare Inc., and Amneal Pharmaceuticals, commenced the sale of generic versions of Lovaza.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved and marketed, would compete with Vascepa. We understand that Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2012 that it intends to conduct a Phase 3 clinical program to

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assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. Acasti has not finalized its definitive Phase 3 program and overall costs and timelines are still contingent upon FDA direction. However, based on their preliminary discussions with FDA, along with Acasti's intent to do a pivotal bioavailability bridging study, Acasti believes that a Phase 3 trial could be initiated in the next 18 months. We believe Catabasis Pharmaceuticals, or Catabasis, Resolvyx Pharmaceuticals, or Resolvyx, and Sancilio & Company are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Catabasis initiated a Phase 2 clinical trial of its product in December 2013 which was completed in May 2015 and subsequently deprioritized and placed on hold in June 2015 and Sancilio is preparing to commence Phase 3 clinical testing in 2016. In addition, we are aware that Matinas BioPharma, Inc. is developing an omega-3-based therapeutic for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Matinas BioPharma, Inc. has filed an Investigational New Drug Application with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia. Ionis (formerly Isis) Pharmaceuticals and Akcea Therapeutics, its subsidiary announced favorable Phase 2 results of volanesorsen (formerly called ISIS-APOCIII$_{Rx}$) a drug candidate administered through weekly subcutaneous injections, in patients with high triglycerides and type 2 diabetes and in patients with moderate to severe high triglycerides. Finally, Madrigal Pharmaceuticals has completed Phase 1 clinical testing of MGL-3196 for the treatment of high triglycerides and various lipid parameters in patients.

Vascepa also faces competition from dietary supplement companies marketing omega-3 products as nutritional supplements. We cannot be sure physicians and pharmacists will view the FDA-approved prescription-only status, EPA-only purity of Vascepa and stringent regulatory oversight as significant advantages versus omega-3 supplements.

In addition, we expect that generic drug companies will seek to challenge the validity and enforceability of our patents and work toward FDA approval for generic versions of Vascepa.

Regulatory Matters

Government Regulation and Regulatory Matters

Any product development activities related to Vascepa or products that we may develop or acquire in the future will be subject to extensive regulation by various government authorities, including the FDA and comparable regulatory authorities in other countries, which regulate the design, research, clinical and non-clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data is generated in two distinct development stages: pre-clinical and clinical. Drugs must be approved by the FDA through the NDA process before they are first marketed in the United States. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies which support subsequent clinical testing.

The clinical stage of development can generally be divided into Phase 1, Phase 2 and Phase 3 clinical trials. In Phase 1, generally, a small number of healthy volunteers are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected. Phase 3 trials generally involve large numbers of patients at multiple sites, in multiple countries and are designed to provide the pivotal data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use, and may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

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United States Drug Development

In the United States, the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Prior to the start of human clinical studies for a new drug in the United States, preclinical laboratory and animal tests are often performed under the FDA's Good Laboratory Practices regulations, or GLP, and an investigational new drug application, or IND, is filed with the FDA. Similar filings are required in other countries; however, data requirements and other information needed for a complete submission may differ in other countries. The amount of data that must be supplied in the IND depends on the phase of the study. Phase 1 studies typically require less data than larger Phase 3 studies. A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. If the FDA has concerns about the clinical plan or the safety of the proposed studies, it may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice and regular reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards, or IRBs, responsible for overseeing studies at particular sites and protecting human research study subjects. An independent IRB may also suspend or terminate a study once initiated.

NDA and FDA Review Process

Following trial completion, trial data is analyzed to determine safety and efficacy. Data is then filed with the FDA in an NDA along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. The NDA must contain proof of safety, purity, potency and efficacy, which entails extensive pre-clinical and clinical testing. FDA approval of an NDA must be obtained before first marketing of a drug in the United States.

The FDA will likely re-analyze the clinical trial data, which could result in iterative discussions between the FDA and us during the review process. The review and evaluation of applications by the FDA is extensive and time consuming and may take longer than originally planned to complete. The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current good manufacturing practice requirements and may also audit data from clinical and pre-clinical trials.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States. Even if future indications for Vascepa are approved, the FDA's review will be lengthy and we may encounter significant difficulties or costs during the review process. After approving any drug product, the FDA may require post-marketing testing and surveillance to monitor the effects of approved products or it may place conditions on approvals including potential requirements or risk management plans that could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Off-label Promotion in the United States

The Federal Food, Drug, and Cosmetic Act, or FDCA, has been interpreted by the FDA to make it illegal for pharmaceutical companies to promote their products for uses that have not been approved by the FDA. Companies that market drugs for so called off-label uses or indications have been subject to related costly litigation, criminal penalties and civil liability under the False Claims Act.

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In May 2015, we and a group of independent physicians filed a lawsuit against the FDA seeking a federal court declaration that would permit us and our agents to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia and promote on the potential of Vascepa to reduce the risk of cardiovascular disease so long as the promotion is truthful and non-misleading. The lawsuit, captioned *Amarin Pharma, Inc., et al. v. Food & Drug Administration, et al.*, S.D.N.Y. (1:15-cv-03588-PAE), was filed in the United States District Court for the Southern District of New York. In the lawsuit, we contend principally that FDA regulations limiting off-label promotion of truthful and non-misleading information are unconstitutional under the freedom of speech clause of the First Amendment as applied in the case of our proposed promotion of Vascepa. The physicians in the suit regularly treat patients at risk of cardiovascular disease and, as the complaint contends, have First Amendment rights to receive truthful and non-misleading information from Amarin. The suit is based on the principle that better informed physicians make better treatment decisions for their patients. This use of Vascepa at issue reflects recognized medical practice but was not approved by the FDA and is thus not covered by current FDA-approved labeling for the drug. It is therefore considered by the FDA to be illegal off-label promotion. The FDA opposed this lawsuit but did not dispute the veracity of the subject ANCHOR clinical trial data, the safety data from which is already in FDA-approved labeling of Vascepa, or the peer-reviewed research related to Vascepa and the potential for cardiovascular risk reduction.

In August 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit through the Court's declaratory judgment that confirmed we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa to healthcare professionals, i.e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the Federal Food and Drug Cosmetic Act. We believe the court declaration permits us to promote to healthcare professionals the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications. We believe this win is in the best interest of patient care because it enables us to more readily supply accurate information to physicians about Vascepa so they can make informed decisions on how to treat patients based on current, scientific data and consistent with numerous national and international cardiovascular treatment guidelines and position statements. In August 2015, we began to promote Vascepa to healthcare professionals as permitted by this court declaration. The FDA did not appeal the court's ruling. The underlying litigation has been stayed for settlement discussion and the parties are working toward settlement. While we are permitted to more broadly promote Vascepa based on this court declaration, the FDA-approved labeling for Vascepa did not change based on the court declaration, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required. Based on our communications with the FDA, we expect that final positive results from the REDUCE-IT outcomes study will be required for label expansion for Vascepa.

Even though we have the benefit of a preliminary federal court declaration and may be ultimately successful with a final settlement or final ruling in this litigation, our promotion would still be subject to a high, perhaps abnormally high, degree of scrutiny to ensure that our promotion remains within the scope covered by the declaration. Federal and state governments may also seek to find other means to prevent our promotion of unapproved truthful and non-misleading information about Vascepa. If our operations are found to be in violation of any of law or governmental regulation through existing or new interpretations, we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Foreign Regulation of New Drug Compounds

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.